

§ 520.1409

is attained, dosage should be gradually reduced until maintenance level is achieved. Hazardous for human use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 52697, Nov. 23, 1982, as amended at 49 FR 20810, May 17, 1984; 50 FR 32844, Aug. 15, 1985; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.1409 Methylprednisolone, aspirin tablets.

(a) *Specifications.* Each tablet contains 0.5 milligram of methylprednisolone and 300 milligrams of aspirin.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. New animal drug applications for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special considerations.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with tuberculosis, chronic nephritis, peptic ulcer, or Cushingoid syndrome. The presence of diabetes mellitus, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) *Conditions of use*—(1) *Amount.* Dogs under 15 pounds, $\frac{1}{4}$ to 1 tablet daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily.

(2) *Indications for use.* As an anti-inflammatory and analgesic agent in dogs.

(3) *Limitations.* Administer total daily dose in divided doses 6 to 10 hours

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apart, with a light feeding. When response is attained, dosage should be gradually reduced until maintenance level is achieved. Do not administer to cats. Do not overdose. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 21566, May 13, 1983]

§ 520.1422 Metoserbate hydrochloride.

(a) *Chemical name.* Methyl-*o*-methyl-18-epireserpate hydrochloride.

(b) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.410 of this chapter.

(d) *Conditions of use.* It is used in drinking water for replacement chickens as follows:

(1) *Amount.* 568.5 milligrams per gallon (0.015 percent).

(i) *Indications for use.* As a tranquilizer for flock treatment of chickens prior to handling.

(ii) *Limitations.* To be used one time as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

(2) *Amount.* 2 to 4 milligrams per 2.2 pounds of body weight.

(i) *Indications for use.* As an aid in control of hysteria.

(ii) *Limitations.* To be used as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; the drug should be administered at a dosage level of 4 milligrams per 2.2 pounds of body weight followed by 2 treatments at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

§ 520.1430 Mibolerone.

(a) *Specifications.* Each milliliter contains 100 micrograms of mibolerone.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.